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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,602	09/29/2003	Carlos Schuler	0076.10	9993
21968 7590 04/16/2008 NEKTAR THERAPEUTICS 201 INDUSTRIAL ROAD SAN CARLOS, CA 94070				
EXAMINER				
PATEL, NIHIR B				
ART UNIT		PAPER NUMBER		
3772				
MAIL DATE		DELIVERY MODE		
04/16/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/675,602

Applicant(s)

SCHULER ET AL.

Examiner

NIHIR PATEL

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02.04.2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed February 4th, 2008 have been fully considered but they are not persuasive. First the applicant argues that Smith does not teach a hole forming device to form an elongate opening in a cover of a receptacle. In response to applicant's arguments, the recitation **"to form an elongate opening in a cover of a receptacle"** has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The applicant further argues that Smith does not teach a movable support member capable of being moved a distance through the cover in a forward direction, or a plurality of outer blades extending in the same forward direction. The examiner disagrees with the applicant's arguments. The movable support member **140** (see **figure 7**) of the Smith reference is capable of being moved a distance through the cover in a forward direction, or a plurality of outer blades **150** extending in the same forward direction.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims **22-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 5,740,794).

5. **As to claims 22-26, 29 and 31**, Smith discloses an apparatus that comprises a movable support member **108 (see figure 10)** capable of being moved a distance through the cover in a forward direction; a plurality of outer blades **(see figure 11A; the walls of flow structures 142 and 146 define the plurality of blades)** extending in the same forward direction, and further extending downward from the support member; a tubular member **140 (see figure 7)** extending downward from the support member with the member being surrounded by the outer blades **(see figure 7)**, and the member having a distal end that includes a plurality of inwardly directed and outwardly facing blades **(see figures 11A; the walls of flow structures 142 and 146 define the plurality of blades)** but does not provide plurality of blades extending downward from the support member at an angle in the range from about 50 to 80 degrees and having a width in the range from about 0.3 to about 2 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Seidler's invention by providing provide plurality of blades extending downward from the support member at an angle in the range from

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about 50 to 80 degrees and having a width in the range from about 0.3 to about 2 mm. Since it has been held that where the general conditions of the claims are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art *In re Aller*, **105 USPQ 233**.

6. **As to claims 27 and 32**, Smith substantially discloses an apparatus that further comprises a gas source that is configured to flow a gas stream through at least a portion of the tubular member to draw gases through the inlet openings, through the cavity and through the tubular member (**see abstract**).

7. **As to claims 28 and 33**, Smith substantially discloses an apparatus that further comprises a mouthpiece, wherein suction on the mouthpiece **32** causes a gas stream to flow at last a portion of the tubular member to draw gases through the inlet openings, through the cavity and through the tubular member (**see column 14 lines 10-45**).

8. **As to claim 30**, Smith substantially discloses an apparatus that further comprises a circular outer periphery, and further comprising a plurality of outer blades that are arranged to form a plurality of inlet openings about the outer periphery to surround the outlet opening (**see figure 11B**).

9. Claims **1-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,740,794).

10. **As to claims 1-11**, Smith substantially discloses method steps of providing a receptacle having a cover with an exterior surface and an interior surface covering a cavity (**see figure 1**); providing a cutting mechanism **140 and 150** (**see figures 10 and 11**) having multiple blades

piercing the cover with the blade (**see column 14 lines 10-45**); moving the blades in a forward direction and across a distance through the cover to cut a portion of the cover to create multiple elongate openings in the cover and thereby provide access into the cavity, with the cut portion being removed away from the cavity as the openings are created (**see column 14 lines 10-45**).

The claimed method step would have been obvious because they would have resulted from the use of the device of Smith.

11. **As to claims 12-20**, Smith substantially discloses method steps of providing a receptacle having a cover with an exterior surface and an interior surface covering a cavity (**see figure 1**) that contains a powder; providing a cutting mechanism **140 and 150** (**see figures 10 and 11**) having at least one outer blade and a plurality of inner blades (**see figures 10 and 11**); piercing the cover with the outer blade and the inner blade (**see column 14 lines 10-45**); moving the outer blade in a forward direction and across a distance through the cover to cut a portion of the cover and to create an outer elongate opening in the cover, with the cut portion being removed away from the cavity as the opening is created, and simultaneously moving the inner blades through the cover to cut an inner opening in the cover; and drawing air through the outer opening through the cavity and out the inner opening to extract the powder from the receptacles and to aerosolize the powder (**see column 14 lines 1-45**).

The claimed method step would have been obvious because they would have resulted from the use of the device of Smith.

12. **As to claim 21**, Smith substantially discloses method steps of providing a receptacle having a cover with an exterior surface and an interior surface covering a cavity (**see figure 1**); providing a cutting mechanism having at least one outer blade and a tubular body having a distal

end with plurality of inwardly directed and outwardly facing blades **140 and 150 (see figures 10 and 11)**; piercing the cover with the blades; and rotating the cutting mechanism across a distance through the cover to form multiple openings in the cover (see **column 14 lines 10-45**).

The claimed method step would have been obvious because they would have resulted from the use of the device of Smith.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **NIHIR PATEL** whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772